



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Data System for Organ Procurement and Transplantation Network, OMB No. 0915-0157 - Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0915-0157 - Revision

Abstract: Section 372 of the Public Health Service Act requires that the Secretary of HHS, by contract, provide for the establishment and operation of a private, non-profit entity the Organ Procurement and Transplantation Network (OPTN), which on behalf of HRSA, operates the U.S. donation and transplantation system. The OPTN Board of Directors (BOD) determines what data must be collected to appropriately fulfill the OPTN responsibilities pursuant to the regulatory authority in 42 CFR 121.11 of the OPTN Final Rule. HRSA, on behalf of the OPTN BOD and in alignment with the Paperwork Reduction Act of 1995, submits OPTN BOD-approved data elements for collection to OMB for official federal approval.

A 60-day notice published in the *Federal Register* on September 29, 2022, vol. 87, No. 188; pp. 59103-59105. HRSA received one comment. The commenter supported the necessity and utility of the proposed information collection and the accuracy of the estimated burden. However, the commenter recommended that HRSA consider enhancements to the ‘currently-used United Network for Organ Sharing data system’ including the need for more real-time data for Organ Procurement Organizations (OPO) and a more advanced application programming interface which integrates with OPO’s electronic medical record platforms. Since the requested changes were to the ‘OPTN data system’ and not the forms themselves, HRSA is not making any changes to the information collection request as a result of this comment. However, HRSA appreciates all public feedback and will consider data system changes in consultation with the OPTN members and the public.

Need and Proposed Use of the Information: HRSA and the OPTN BOD use data to

develop transplant, donation, and allocation policies; to determine whether institutional members are complying with policy; to determine member-specific performance; to ensure patient safety, and to fulfill the requirements of the OPTN Final Rule. In addition, the regulatory authority in 42 CFR 121.11 of the OPTN Final Rule requires the OPTN data to be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, HHS, and members of the public for evaluation, research, patient information, and other important purposes.

This is a request to revise the current OPTN data collection which includes time-sensitive, life-critical data on transplant candidates and donors, the organ matching process, histocompatibility results, organ labeling, and packaging, and pre-and post-transplantation data on recipients and donors. This revision also includes OPTN BOD-approved changes to the existing OMB data collection forms. The OPTN collects these specific data elements from transplant hospitals, OPOs, and histocompatibility laboratories.

The OPTN uses this information to: (1) facilitate organ placement and match donor organs with recipients, (2) monitor compliance of member organizations with federal laws and regulations and with OPTN requirements, (3) review and report periodically to the public on the status of organ donation and transplantation in the United States, (4) provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation, and (5) perform transplantation-related public health surveillance including the possible transmission of donor disease.

HRSA is requesting to make the following OPTN BOD-approved changes to improve the OPTN organ matching and allocation process and improve OPTN member compliance with OPTN requirements:

- (1) Adding data collection forms from the OPTN donor management and organ matching system to the existing OMB-approved information collection. The system allows an OPO to add donors, run the donor/potential transplant recipients matches, and place a

donated organ(s) with a computer-matched potential transplant recipient. Transplant centers will access the system to view posted donor information to assist them with accepting decisions, along with other donor/potential transplant recipient functions such as entering offer responses and verifying organ offer refusals. The OPTN donor management and organ matching system is comprised of eight data collection forms: initial donor registration, OPO notification limit administration, potential transplant recipient, death notification registration, deceased donor death referral, donor hospital registration, donor organ disposition, and transplant center contact management.

- (2) The OPTN BOD-approved additional revisions to existing data collection forms to improve organ matching, allocation, and OPTN policy compliance.
- (3) Existing OPTN data collection forms that collect a single race and ethnicity variable will be revised to collect separate race and ethnicity variables, following the minimum standards for collecting and presenting data on race and ethnicity for all federal reporting found within Revisions of Standards for the Classification of Federal Data on Race and Ethnicity, OMB Statistical Policy Directive No. 15 in Federal Register, 62 FR 58782 (Oct. 30, 1997). Improving data collection around race and ethnicity information of donors and candidates aligns with Executive Order 13985, which calls on agencies to advance equity through identifying and addressing barriers to equal opportunity that underserved communities may face due to government policies and programs.

Likely Respondents: Transplant Programs, OPOs, and Histocompatibility Laboratories.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to

respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The total estimated burden hours for this collection increased by 217,361.30 hours from the previously OMB-approved data collection package from March 22, 2022. This increase is for the most part due to the addition of eight collection forms from the OPTN donor management and organ matching system to this data collection package, specifically the burden increases from the Potential Transplant Recipient form. While the data fields collected on the Potential Transplant Recipient form are limited, the volume of organ offer responses is significant due to the large number of potential transplant recipients shown on the organ match run results. The organ match run results produce thousands of potential transplant recipients that require responses from OPOs and transplant hospitals. This volume of candidates significantly impacts the total burden hours for this form.

Total Estimated Annualized Burden Hours:

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Deceased Donor Registration	57	243.56	13,883	1.20	16,659.60
Living Donor Registration	216	28.11	6,072	2.19	13,297.68
Living Donor Follow-up	216	90.55	19,559	1.52	29,729.68
Donor Histocompatibility	141	149.18	21,034	0.20	4,206.80
Recipient Histocompatibility	141	264.95	37,358	0.40	14,943.20
Heart Transplant Candidate Registration	145	34.59	5,016	0.90	4,514.40

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Heart Transplant Recipient Registration	145	26.32	3,816	1.96	7,479.36
Heart Transplant Recipient Follow Up (6 Month)	145	24.40	3,538	0.40	1,415.20
Heart Transplant Recipient Follow Up (1-5 Year)	145	104.14	15,100	0.90	13,590.00
Heart Transplant Recipient Follow Up (Post 5 Year)	145	171.10	24,810	0.50	12,405.00
Heart Post-Transplant Malignancy Form	145	13.17	1,910	0.90	1,719.00
Lung Transplant Candidate Registration	72	42.97	3,094	0.90	2,784.60
Lung Transplant Recipient Registration	72	35.01	2,521	1.20	3,025.20
Lung Transplant Recipient Follow Up (6 Month)	72	33.63	2,421	0.50	1,210.50
Lung Transplant Recipient Follow Up (1-5 Year)	72	139.94	10,076	1.10	11,083.60
Lung Transplant Recipient Follow Up (Post 5 Year)	72	136.28	9,812	0.60	5,887.20
Lung Post-Transplant Malignancy Form	72	22.63	1,629	0.40	651.60
Heart/Lung Transplant	70	0.96	67	1.10	73.70

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Candidate Registration					
Heart/Lung Transplant Recipient Registration	70	0.64	45	2.15	96.75
Heart/Lung Transplant Recipient Follow Up (6 Month)	70	0.60	42	0.80	33.60
Heart/Lung Transplant Recipient Follow Up (1-5 Year)	70	2.10	147	1.10	161.70
Heart/Lung Transplant Recipient Follow Up (Post 5 Year)	70	3.36	235	0.60	141.00
Heart/Lung Post-Transplant Malignancy Form	70	0.29	20	0.40	8.00
Liver Transplant Candidate Registration	143	96.92	13,860	0.80	11,088.00
Liver Transplant Recipient Registration	143	64.58	9,235	1.20	11,082.00
Liver Transplant Recipient Follow Up (6 Month - 5 Year)	143	320.27	45,799	1.00	45,799.00
Liver Transplant Recipient Follow Up (Post 5 Year)	143	384.32	54,958	0.50	27,479.00
Liver Recipient Explant Pathology Form	143	7.30	1,044	0.60	626.40

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Liver Post-Transplant Malignancy	143	19.06	2,726	0.80	2,180.80
Intestine Transplant Candidate Registration	21	6.86	144	1.30	187.20
Intestine Transplant Recipient Registration	21	4.57	96	1.80	172.80
Intestine Transplant Recipient Follow Up (6 Month - 5 Year)	21	20.05	421	1.50	631.50
Intestine Transplant Recipient Follow Up (Post 5 Year)	21	40.19	844	0.40	337.60
Intestine Post-Transplant Malignancy Form	21	0.62	13	1.00	13.00
Kidney Transplant Candidate Registration	234	177.00	41,418	0.80	33,134.40
Kidney Transplant Recipient Registration	234	105.40	24,664	1.20	29,596.80
Kidney Transplant Recipient Follow Up (6 Month - 5 Year)	234	517.12	121,006	0.90	108,905.40
Kidney Transplant Recipient Follow Up (Post 5 Year)	234	525.10	122,873	0.50	61,436.50

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Kidney Post-Transplant Malignancy Form	234	24.47	5,726	0.80	4,580.80
Pancreas Transplant Candidate Registration	120	2.65	318	0.60	190.80
Pancreas Transplant Recipient Registration	120	1.19	143	1.20	171.60
Pancreas Transplant Recipient Follow Up (6 Month - 5 Year)	120	6.68	802	0.50	401.00
Pancreas Transplant Recipient Follow Up (Post 5 Year)	120	17.82	2138	0.50	1,069.00
Pancreas Post-Transplant Malignancy Form	120	1.06	127	0.60	76.20
Kidney/Pancreas Transplant Candidate Registration	120	12.45	1,494	0.60	896.40
Kidney/Pancreas Transplant Recipient Registration	120	6.84	821	1.20	985.20
Kidney/Pancreas Transplant Recipient Follow Up (6 Month - 5 Year)	120	39.44	4,733	0.50	2,366.50

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Kidney/Pancreas Transplant Recipient Follow Up (Post 5 Year)	120	69.41	8,329	0.60	4,997.40
Kidney/Pancreas Post-Transplant Malignancy Form	120	2.49	299	0.40	119.60
Vascularized Composite Allograft (VCA) Transplant Candidate Registration	21	0.33	7	0.40	2.80
VCA Transplant Recipient Registration	21	0.19	4	1.36	5.44
VCA Transplant Recipient Follow Up	21	1.00	21	1.31	27.51
Organ Labeling and Packaging	57	247.72	14,120	0.18	2,541.60
Organ Tracking and Validating	308	19.49	6,003	0.08	480.24
Kidney Paired Donation Candidate Registration	159	1.20	191	0.29	55.39
Kidney Paired Donation Donor Registration	159	1.56	248	1.08	267.84
Kidney Paired Donation Match Offer Management	159	1.52	242	0.67	162.14
Disease Transmission Event	308	1.81	557	0.62	345.34

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Living Donor Event	251	0.156	39	0.56	21.84
Safety Situation	449	0.60	269	0.56	150.64
Potential Disease Transmission	57	8.72	497	1.27	631.19
Request to Unlock Form	449	42.40	19,038	0.02	380.76
Initial Donor Registration	57	335.72	19,136	3.00	57,408.00
OPO Notification Limit Administration	57	0.49	28	0.17	4.76
Potential Transplant Recipient	308	4718.48	1,453,292	0.05	72,664.60
Death Notification Registration	57	185.77	10,589	0.42	4,447.38
Deceased Donor Death Referral	57	53.84	3,069	0.50	1,534.50
Donor Hospital Registration	57	0.04	2	0.08	0.16
Donor Organ Disposition	57	335.72	19,136	0.17	3,253.12
Transplant Center Contact Management	251	637.50	160,013	0.06	9,600.78
Total = 70 forms	9,146		2,352,737		647,628.30

* The numbers of respondents and the numbers of total responses in the burden table were updated with 2021 OPTN data and reflect increases in the number of organ transplants and changes in the number of respondents (Transplant Programs, OPO, and Histocompatibility Labs).

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of

the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

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